DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 8 2009

Re: MIRCERA
Docket No.: FDA-2008-E-0107

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,583,272, filed by Hoffmann-La Roche Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for MIRCERA (methoxy polyethylene glycol-epoetin beta), the human biological product claimed by the patent.

The total length of the regulatory review period for MIRCERA (methoxy polyethylene glycol-epoetin beta) is 2,140 days. Of this time, 1,565 days occurred during the testing phase and 575 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 6, 2002.

   The applicant claims January 3, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 6, 2002, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: April 19, 2006.

   The applicant claims April 18, 2006, as the date the biologics license application (BLA) for MIRCERA (BLA B125164/0) was initially submitted. However, FDA records indicate that BLA B125164/0 was submitted on April 19, 2006.

3. The date the application was approved: November 14, 2007.

   FDA has verified the applicant's claim that BLA B125164/0 was approved on November 14, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: George W. Johnston
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